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CLAIMS

1. An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10% organic solvent and has a pH of about 3.0 to about 4.8.

2. The composition of claim 1, wherein the serum albumin is undefatted.

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- 3. The composition of claim 1, wherein the composition has been lyophilized or lyophilized and then reconstituted from the lyophilized formulation.
- 4. An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, defatted serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises about 10% or less organic solvent.
- 5. The composition as claimed in any one of 1 to 4, wherein at least 70% of the paclitaxel or derivative thereof introduced into the composition is bound to the serum albumin.
 - 6. The composition as claimed in any one of claims 1 to 4, wherein at least 80% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.
 - 7. The composition as claimed in any one of claims 1 to 4, wherein at least 85% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.
 - 8. The composition as claimed in any one of claims 1 to 4, wherein at least 90% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.
 - 9. The composition as claimed in any one of claims 1 to 8, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:5.
 - 10. The composition as claimed in claim 9, wherein the ratio of paclitaxel or derivative thereof to albumin is greater than 1:4.
 - 11. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:4.
- 30 12. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:2.

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13. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:1.

- 14. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:1 to about 2:1.
- 5 15. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 25 μg/ml.
 - 16. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 50 μg/ml
 - 17. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 100 µg/ml.

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- 18. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 200 μg/ml.
- , 19. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 300 μg/ml.
- 20. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 400 μg/ml.
 - 21. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 500 μg/ml.
 - 22. The composition as claimed in any of claims 1 to 21, wherein the concentration of organic solvent is about 1 to about 10% v/v.
 - 23. The composition of claim 22, wherein the concentration of organic solvent is about 2 to about 8% v/v.
 - 24. The composition of claim 23, wherein the concentration of organic solvent is about 4 to about 6% v/v.
- 25. The composition of claim 3, wherein the composition is essentially free of organic solvent.
 - 26. The composition as claimed in any of claims 1 to 24, wherein the organic solvent is alcohol.
 - 27. The composition of claim 26, wherein the alcohol is ethanol.
- 30 28. The composition as claimed in any of claims 1 to 27, wherein the pH is about 3.0 to about 4.8.
 - 29. The composition of claim 28, wherein the pH is about 4.0 or less.

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30. The composition of claim 29, wherein the pH is less than about 4.0.

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- 31. The composition of claim 30, wherein the pH is about 3.4 to about 3.8.
- 32. The composition of claim 1, wherein the serum albumin is at least about 80% to about 90% monomeric.
- 33. A lyophilized preparation of an optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:4, and wherein the composition comprises less than 10% organic solvent and has a pH of about 3.0 to about 4.8 upon reconstitution, and wherein at least about 70% of the paclitaxel introduced into the composition is bound to the serum albumin and wherein the paclitaxel concentration in the composition is at least 50 μg/ml.
 - 34. A method of treatment, comprising administering to a patient in a pharmaceutically acceptable form a therapeutically effective amount of a composition as claimed in any of claims 1 to 33.
 - 35. A method of making a composition as claimed in any of claims 1 to 33, comprising the steps of: preparing a solution of the paclitaxel or a derivative thereof; preparing a solution of serum albumin; and slowly combining the solutions, and optionally lyophilizing or optionally lyophilizing and reconstituting the combined solutions.
- 36. The method of claim 35, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:1, and the solutions are combined at a temperature below room temperature.
 - 37. The method of claim 35, wherein the ratio or paclitaxel or derivative thereof to albumin is about 1:1, and the solutions are combined at a temperature of about 2 to about 8°C.
 - 38. The method of claim 35, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:1, and solutions are combined at a temperature of about 4°C.
 - 39. A composition as claimed in any of claims 1 to 33, wherein the desired dose can be administered in a period of less than 3 hours.
- 40. A composition as claimed in any of claims 1 to 33, wherein the desired dose can be administered in a period of less than 2 hours.

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41. The method as claimed in any of claims 35 to 38, wherein the solution of paclitaxel is added dropwise at a controlled rate.

- 42. The method as claimed in any of claims 35 to 38, wherein the solution of paclitaxel is added at a rate of about 1 ml/minute or slower and the drop size is 8 to 20 μl.
- 43. A method of treatment, comprising administering to a patient a therapeutically effective amount of an optically clear, pharmaceutically acceptable aqueous composition comprising a hydrophobic drug, a globulin and a pharmaceutically acceptable vehicle, where the drug and the globulin are present in at least about approximately a 1:2 molar ratio.
- 44. A composition comprising a therapeutically effective amount of an optically clear, pharmaceutically acceptable, aqueous composition comprising a hydrophobic drug, a globulin, and a physiologically acceptable vehicle wherein the drug and globulin are present at about a 1:2 molar ratio and the pH is at or below the pI of the globulin.
- 45. A method of making an optically clear, pharmaceutically acceptable, aqueous composition of a hydrophobic drug, a globulin, and a physiologically acceptable vehicle, comprising the steps of: preparing a solution of the globulin; preparing a solution of drug; and slowly adding the drug solution to the globulin solution, where the globulin solution is at or below the pI of the globulin.